

Establishment Inspection Report

Bayer Medical Care, Inc.
Saxonburg, PA 16056-9772

FEI: **3006791331**
EI Start: 1/18/2017
EI End: 1/19/2017

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SUMMARY

This pre-announced, routine, surveillance inspection of a medical device manufacturer was conducted under Operation ID # 51415, and in accordance with Compliance Programs 7382.845B and 7881.011, Inspection of Medical Device Manufacturers. The previous inspection was conducted on 08/06-07/2013, and was classified NAI.

This firm manufactures sterile disposable medical device products as accessories/components to their radiological delivery system capital equipment medical devices. Various quality and design control activities are managed at this firm's Indianola, PA facility. During this inspection, management controls, corrective and preventive actions, and production and process controls were reviewed.

Management was cooperative and made no refusals, and no FDA Form 483 was issued.

ADMINISTRATIVE DATA

Inspected firm:	Bayer Medical Care, Inc.
Location:	150 Victory Rd Saxonburg, PA 16056-9772
Phone:	724-360-7602
FAX:	412-406-0665
Mailing address:	150 Victory Rd Saxonburg, PA 16056-9772
Dates of inspection:	1/18/2017-1/19/2017
Days in the facility:	2

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Participants: **Katelyn A Staub-Zamperini, Investigator**

At the beginning of this inspection, credentials were presented and an FDA Form 482, Notice of Inspection, was issued to William E. Bullis, Vice President, who identified himself as the most responsible individual at this location.

HISTORY

This firm is owned by Bayer Healthcare, and is part of the Bayer Radiology group under Bayer's Pharmaceuticals Division. This firm is registered with the FDA as Bayer Medical Care, Inc. and operates as Bayer Medrad.

This firm currently maintains approximately (b) (4) employees, and operates (b) (4) per day, (b) (4) days per week. This firm's annual production of sterile disposable products is approximately (b) (4) syringes. Future FDA correspondence should be addressed to, William E. Bullis, Vice President, and sent to:

1 Bayer Drive
Indianola, PA 15051

INTERSTATE (I.S.) COMMERCE

This firm utilizes the distributor, (b) (4) located in (b) (4). Products are then further distributed throughout the United States, as well as internationally.

JURISDICTION (PRODUCTS MANUFACTURED AND/OR DISTRIBUTED)

This firm maintains a medical device registration with the FDA as a manufacturer. This firm manufactures sterile disposable medical device products, and firm management stated that the main products produced are Stellant syringes and disposables. Firm management provided a product list (**Exhibit # 1**) and a Stellant CT Syringe Kits and Connector Tubing Instructions for Use document (**Exhibit # 2**).

This firm utilizes a highly automated manufacturing process. Firm management explained that key technologies utilized are clean room syringe assembly, (b) (4) packaging, and (b) (4).

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

William E. Bullis, Vice President, Julia Mitchell, (b) (6) (b) (6) were present during the close-out discussions and at various parts of this inspection, and provided relevant information.

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(b) (6), Quality Business Partner Medical Devices was present during the close-out discussions via telephone and (b) (6), Quality Product Steward was present for this entire inspection and provided relevant information.

William (Bill) E. Bullis, Vice President, is the most responsible individual at this firm, and is responsible for all day-to-day operations. Individual responsibility and corporate organizational structure is covered in more detail in the establishment inspection report of this firm's Indianola, PA facility.

MANUFACTURING/DESIGN OPERATIONS

This firm utilizes a highly automated manufacturing process. Firm management explained that key technologies utilized are clean room syringe assembly, (b) (4) packaging, and (b) (4).

During this inspection, management controls, production and process controls, and corrective and preventive actions were reviewed. Inspectional coverage of each subsystem is as follows:

Management Controls: (b) (4) quality review meeting documentation, specific to this facility, was reviewed.

Production and Process Controls: Component specifications, incoming inspection activities, and supplier controls were reviewed. Manufacturing equipment preventative maintenance plans/schedules and documentation was reviewed. Sterility processing records were also reviewed.

Corrective and Preventive Action: Various nonconformance reports and supplier corrective action request reports were reviewed.

EXHIBITS COLLECTED

- 1 Exhibit 1, Product List, 1 page
- 2 Exhibit 2, Instructions for Use, 12 pages

ATTACHMENTS

- 1 FDA Form 482, Notice of Inspection, 3 pages

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3/9/2017

X Katelyn A Staub-Zamperini

Katelyn A Staub-Zamperini

Investigator

Signed by: Katelyn A. Staub-zamperini -S